

EV 746095803 US

July 27, 2006

USPS Express Mail Label Number

Date of Deposit

I hereby certify that this correspondence is being deposited with the United States Postal Services "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to the Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By:

Nancy Foster



PATENT

Customer No. 22,852

Attorney Docket No. 04012.0373-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

R. W. ESMOND et al.

Application No.: 09/394,712

Filed: September 13, 1999

For: METHOD FOR TREATING OR
PREVENTING ALZHEIMER'S
DISEASE

)
)
) Group Art Unit: 1614
)
) Examiner: Vickie Y. KIM
)
)
) Confirmation No.: 4740
)
)

MAIL STOP RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

EIGHTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the enclosed IDS Form PTO/SB/08. This Information Disclosure Statement is being filed with a Request for Continued Examination.

Copies of the listed documents are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.


Applicants further reserve the right to take appropriate action to establish the patentability of the claimed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 27, 2006

By: 
Michael R. Albrecht
Reg. No. 54,956
Customer No. 22,852

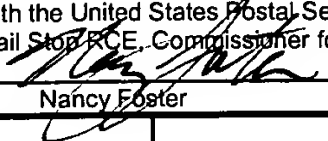
EV 746095803 US

July 27, 2006

USPS Express Mail Label Number

Date of Deposit

I hereby certify that this correspondence is being deposited with the United States Postal Services "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to the Mail Stop PCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: 
Nancy Foster

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

Complete if Known**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

3

Application Number	09/394,712
Filing Date	September 13, 1999
First Named Inventor	R. W. ESMOND et al.
Art Unit	1614
Examiner Name	Vickie Y. KIM
Attorney Docket Number	04012.0373-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

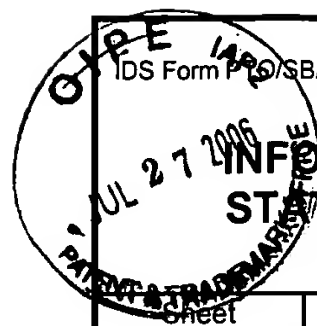
Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				

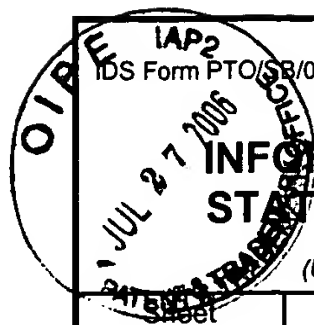
NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶
		BEAL et al., "Somatostatin: alterations in the central nervous system in neurological diseases," <i>Res. Publ. Assoc. Res. Nerv. Ment. Dis.</i> , 64: 215-257 (1986).	
		BROE et al., "A case-control study of Alzheimer's disease in Australia," <i>Neurology</i> 40: 1698-1707 (1990).	
		BUCHT et al., "Changes in blood glucose and insulin secretion in patients with senile dementia of Alzheimer type," <i>Acta Med. Scand.</i> , 213: 387-392 (1983).	
		BURGERING et al., "Protein kinase B (c-Akt) in phosphatidylinositol-3-OH kinase signal transduction," <i>Nature</i> , 376: 599-602 (1995).	
		CANTELO et al., "The synthesis of BRL 49653 - a novel and potent antihyperglycaemic agent," <i>Bioorg. Med. Chem. Lett.</i> , 4: 1181-1184 (1994).	
		CARSON et al., "Insulin-like growth factor I increases brain growth and central nervous system myelination in transgenic mice," <i>Neuron</i> , 10: 729-740 (1993).	
		CREWS et al., "Binding of [¹²⁵ I]-insulin-like growth factor-1 (IGF-1) in brains of Alzheimer's and alcoholic patients," <i>Adv. Exp. Med. Biol.</i> , 293: 483-492 (1991).	
		CREWS et al., "Insulin-like growth factor I receptor binding in brains of Alzheimer's and alcoholic patients," <i>J. Neurochem.</i> , 58: 1205-1210 (1992).	
		CURB et al., "The relationship of diabetes and glucose tolerance to Alzheimer's disease and vascular dementia," <i>Neurobiol. Aging</i> , 17(4S): S122 [Abstract 488] (1996).	
		D'ERCOLE et al., "Use of transgenic mice for understanding the physiology of insulin-like growth factors," <i>Horm. Res.</i> , 45 (Suppl.1): 5-7 (1996).	
		D'ERCOLE et al., "The role of the insulin-like growth factors in the central nervous system," <i>Mol. Neurobiol.</i> , 13: 227-255 (1996).	
		De KEYSER et al., "Insulin-like growth factor-I receptor densities in human frontal cortex and white matter during aging, in Alzheimer's disease, and in Huntington's disease," <i>Neurosci. Lett.</i> , 172: 93-96 (1994).	
		de la MONTE et al., "Modulation of neuronal thread protein expression with neuritic sprouting: relevance to Alzheimer's disease," <i>Journal of the Neurological Sciences</i> , 138: 26-35 (1996).	
		de la MONTE et al., "Profiles of neuronal thread protein expression in Alzheimer's disease," <i>Journal of Neuropathology and Experimental Neurology</i> , 55: 1038-1050 (1996).	
		de la MONTE et al., "Characterization of the AD7C-NTP cDNA expression in Alzheimer's disease and measurement of a 41-kD protein in cerebrospinal fluid," <i>J. Clin. Invest.</i> , 100: 3093-3104 (1997).	
		de la MONTE et al., "Neuronal thread protein gene modulation with cerebral infarction," <i>Journal of Cerebral Blood Flow & Metabolism</i> , 17:623-635 (1997).	



IDS Form P-01/08: Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	09/394,712
		Filing Date	September 13, 1999
		First Named Inventor	R. W. ESMOND et al.
		Art Unit	1614
		Examiner Name	Vickie Y. KIM
		Attorney Docket Number	04012.0373-00000
Sheet	2	of	3

NON PATENT LITERATURE DOCUMENTS			
		DUDEK et al., "Regulation of neuronal survival by the serine-threonine protein kinase Akt," <i>Science</i> , 275: 661-665 (1997).	
		DUELLI et al., "Intracerebroventricular injection of streptozotocin induces discrete local changes in cerebral glucose utilization in rats," <i>Int. J. Devl. Neuroscience</i> , 12:737-743 (1994).	
		FERINI-STRAMBI et al., "Clinical and epidemiological aspects of Alzheimer's disease with presenile onset: a case-control study," <i>Neuroepidemiology</i> , 9: 39-49 (1990).	
		FINCH et al., "Aging, metabolism, and Alzheimer disease: Review and hypotheses," <i>Experimental Neurology</i> , 143: 82-102 (1997).	
		FISMAN et al., "Metabolic changes in Alzheimer's disease," <i>J. Am. Geriatr. Soc.</i> , 36: 298-300 (1988).	
		FOLLI et al., "The early intracellular signaling pathway for the insulin/insulin-like growth factor receptor family in the mammalian central nervous system," <i>Mol. Neurobiol.</i> , 13: 155-183 (1996).	
		FUJISAWA et al., "Increased insulin levels after OGTT load in peripheral blood and cerebrospinal fluid of patients with dementia of Alzheimer type," <i>Biol. Psychiatry</i> , 30: 1219-1228 (1991).	
		GARVER et al., "Tau phosphorylation in brain slices: pharmacological evidence for convergent effects of protein phosphatases on tau and mitogen-activated protein kinase," <i>Mol. Pharmacol.</i> , 47: 745-756 (1995).	
		GLENNER et al., "Alzheimer's disease: initial report of the purification and characterization of a novel cerebrovascular amyloid protein," <i>Biochem. Biophys. Res. Commun.</i> , 120: 885-890 (1984).	
		GOTTFRIES, "Therapy options in Alzheimers-Disease," <i>Brit. J. Clin. Practice</i> , 48(6):327-330 (1994).	
		HEIDENREICH et al., "Insulin receptors mediate growth effects in cultured fetal neurons. I. Rapid stimulation of protein synthesis," <i>Endocrinology</i> , 125: 1451-1457 (1989).	
		HEYMAN et al., "Alzheimer's disease: A study of epidemiological aspects," <i>Ann. Neurol.</i> , 15: 335-341 (1984).	
		HIRSCH et al., "Mitochondrial permeability transition in apoptosis and necrosis," <i>Cell Biol. Toxicol.</i> , 14: 141-145 (1998).	
		HOYER et al., "Predominant abnormality in cerebral glucose utilization in late-onset dementia of the Alzheimer type: a cross-sectional comparison against advanced late-onset and incipient early-onset cases," <i>J. Neural Transm. [P-D Sect]</i> , 3: 1-14 (1991).	
		HOYER et al., "Cerebral excess release of neurotransmitter amino acids subsequent to reduced cerebral glucose metabolism in early-onset dementia of Alzheimer type," <i>J. Neural Transm.</i> , 75: 227-232 (1989).	
		HOYER, "Somatostatin and Alzheimer's disease," <i>J. Neurol.</i> , 234: 266-267 (1987).	
		HOYER, "Age as risk factor for sporadic dementia of the Alzheimer type?," <i>Ann. NY Acad. Sci.</i> , 719: 248-256 (1994).	
		HOYER, "Neurodegeneration, Alzheimer's disease, and beta-amyloid toxicity," <i>Life Sci.</i> , 55: 1977-1983 (1994).	
		KOKMEN et al., "Clinical risk factors for Alzheimer's disease: a population-based case-control study," <i>Neurology</i> , 41:1393-1397 (1991).	
		KULIK et al., "Antiapoptotic signalling by the insulin-like growth factor I receptor, phosphatidylinositol 3-kinase, and Akt," <i>Mol. Cell. Biol.</i> , 17: 1595-1606 (1997).	
		LAM et al., "The phosphatidylinositol 3-kinase serine kinase phosphorylates IRS-1. Stimulation by insulin and inhibition by Wortmannin," <i>J. Biol. Chem.</i> , 269: 20648-20652 (1994).	
		LANDIN et al., "Low blood pressure and blood glucose levels in Alzheimer's disease evidence for a hypometabolic disorder?" <i>J. Intern. Med.</i> , 233: 357-363 (1993).	
		LEIBSON et. al., "Risk of dementia among persons with diabetes mellitus: a population-based cohort study," <i>Am. J. Epidemiol.</i> , 145:301-308 (1997).	
		LORENZO et al., "Amyloid fibril toxicity in Alzheimer's disease and diabetes," <i>Ann. NY Acad. Sci.</i> , 777: 89-95 (1996).	
		LOVESTONE et al., "Alzheimer's disease-like phosphorylation of the microtubule-associated protein tau by glycogen synthase kinase-3 in transfected mammalian cells," <i>Curr. Biol.</i> , 4: 1077-1086 (1994).	
		MANDELKOW et al., "Tau protein and Alzheimer's disease," <i>Neurobiology of Aging</i> , 15(2):S85-S86 (1994).	
		McDERMOTT et al., "Degradation of Alzheimer's β -amyloid protein by human and rat brain peptidases: involvement of insulin-degrading enzyme," <i>Neurochem Res.</i> , 22: 49-56 (1997).	
		MENEILLY et al., "Alterations in glucose metabolism in patients with Alzheimer's disease," <i>J. Am. Geriatr. Soc.</i> , 41: 710-714 (1993).	
		MESSIER et al., "Glucose regulation and cognitive functions: relation to Alzheimer's disease and diabetes," <i>Behav. Brain Res.</i> , 75: 1-11 (1996).	
		MILL et al., "Insulin, insulin-like growth factor II, and nerve growth factor effects on tubulin mRNA levels and	



IDS Form PTO/SB/08: Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	09/394,712
		Filing Date	September 13, 1999
		First Named Inventor	R. W. ESMOND et al.
		Art Unit	1614
		Examiner Name	Vickie Y. KIM
		Attorney Docket Number	04012.0373-00000
Sheet	3	of	3

NON PATENT LITERATURE DOCUMENTS			
		neurite formation," <i>Proc. Natl. Acad. Sci. USA</i> , 82: 7126-7130 (1985).	
		MOROO et al., "Loss of insulin receptor immunoreactivity from the substantia nigra pars compacta neurons in Parkinson's disease," <i>Acta Neuropathol.</i> , 87: 343-348 (1994).	
		MORTEL et al., "Analysis of familial and individual risk factors among patients with ischemic vascular dementia and Alzheimer's disease," <i>Angiology</i> , 44: 599-605 (1993).	
		NIELSON et al., "Apolipoprotein-E genotyping of diabetic dementia patients: Is diabetes rare in Alzheimer's disease," <i>J. Am. Geriatr. Soc.</i> , 44: 897-904 (1996).	
		NILLNI et al., "Identification of the thyrotropin-releasing hormone precursor, its processing products, and its coexpression with convertase 1 in primary cultures of hypothalamic neurons: anatomic distribution of PC1 and PC2," <i>Endocrinology</i> , 137: 5651-5661 (1996).	
		NISHIYAMA et al., "Expression of the gene encoding the tyrosine kinase-deficient human insulin receptor in transgenic mice," <i>Gene</i> , 141: 187-192 (1994).	
		O'HARE et al., "Intrinsic kinase activity of the insulin receptor," <i>Int. J. Biochem.</i> , 22: 315-324 (1990).	
		OTT et al., "Association of diabetes mellitus and dementia: the Rotterdam Study," <i>Diabetologia</i> , 39: 1392-1397 (1996).	
		PLASCHKE et al., "Action of the diabetogenic drug streptozotocin on glycolytic and glycogenolytic metabolism in adult rat brain cortex and hippocampus," <i>Int. J. Dev. Neurosci.</i> , 11: 477-483 (1993).	
		PURO et al., "Insulin-mediated regulation of neuronal maturation," <i>Science</i> , 225: 1170-1172 (1984).	
		REUBI et al., "Somatostatin and Alzheimer's disease: a hypothesis," <i>J. Neurol.</i> , 233: 370-372 (1986).	
		SPINDLER et al., "Nutritional status of patients with Alzheimer's disease: a 1-year study," <i>J. Am. Diet Assoc.</i> , 96: 1013-1018 (1996).	
		SUN et al., "Structure of the insulin receptor substrate IRS-1 defines a unique signal transduction protein," <i>Nature</i> , 352: 73-77 (1991).	
		SUN et al., "Pleiotropic insulin signals are engaged by multisite phosphorylation of IRS-1," <i>Mol. Cell. Biol.</i> , 13: 7418-7428 (1993).	
		THAM et al., "Insulin-like growth factors and somatomedin B in the cerebrospinal fluid of patients with dementia of the Alzheimer type," <i>Acta Psychiatr. Scand.</i> , 77: 719-723 (1988).	
		THAM et al., "Insulin-like growth factors and insulin-like growth factor binding proteins in cerebrospinal fluid and serum of patients with dementia of the Alzheimer type," <i>J. Neural Transm. [P-D Sect.]</i> , 5: 165-176 (1993).	
		THORPE et al., "Comorbidity of the other chronic age-dependent diseases in dementia," <i>Aging Clin. Exp. Res.</i> , 6: 159-166 (1994).	
		ULLRICH et al., "Human insulin receptor and its relationship to the tyrosine kinase family of oncogenes," <i>Nature</i> , 313: 756-761 (1985).	
		UNGER et al., "Insulin receptors in the central nervous system: localization, signalling mechanisms and functional aspects," <i>Prog. Neurobiol.</i> , 36: 343-362 (1991).	
		UNGER et al., "Immunohistochemical localization of insulin receptors and phosphotyrosine in the brainstem of the adult rat," <i>Neuroscience</i> , 42: 853-861 (1991).	
		WHITE et al., "Insulin rapidly stimulates tyrosine phosphorylation of a M _r 185,000 protein in intact cells," <i>Nature</i> , 318: 183-186 (1985).	
		WINOGRAD et al., "Blood glucose and insulin response in patients with senile dementia of the Alzheimer's type," <i>Biol. Psychiatry</i> , 30: 507-511 (1991).	
		WOLF-KLEIN et al., "Are Alzheimer patients healthier?" <i>J. Am. Geriatr. Soc.</i> , 36: 219-224 (1988).	
		WOZNIAK et al., "The cellular and physiological actions of insulin in the central nervous system," <i>Neurochem. Int.</i> , 22: 1-10 (1993).	
		XU et al., "Ethanol inhibits insulin receptor substrate-1 tyrosine phosphorylation and insulin-stimulated neuronal thread protein gene expression," <i>Biochem. J.</i> , 310:125-132 (1995).	
		YE et al., "In vivo actions of insulin-like growth factor-I (IGF-I) on cerebellum development in transgenic mice: evidence that IGF-I increases proliferation of granule cell progenitors," <i>Dev. Brain Res.</i> , 95: 44-54 (1996).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.